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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,224	10/27/2000	Peter A. Rice	BOS/3	8386

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/12/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/699,224	RICE ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *17-31* is/are withdrawn from consideration.

5)☒ Claim(s) *16* is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 08/26/03 (paper no. 15) in response to the non-final Office Action mailed 02/26/03 (paper no. 13). With this, Applicants have amended the specification.

Status of Claims

2) Claims 1, 10 and 11 have been amended via the amendment filed 08/26/03.

Claims 1-31 are pending.

Claims 1-16 are under examination.

Declarations

3) Acknowledgment is made of Applicants' Declarations filed 08/26/03 (paper no. 16) under 37 CFR 1.131 and 1.132, which have been considered.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

6) The objection to the specification made in paragraph 8 of the office Action mailed 02/26/03 (paper no. 13) is withdrawn in light of Applicants' amendments to the specification.

Objection(s) Maintained

7) The objection to the drawings made in paragraph 6 of the Office Action mailed 02/26/03 (paper no. 13) under 37 C.F.R 1.84 is maintained for reasons set forth therein.

Rejection(s) Withdrawn

8) The rejection of claims 1 and 11 made in paragraph 11 of the Office Action mailed 02/26/03 (paper no. 13) under 35 U.S.C. § 101 as being directed to a non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claims.

9) The rejection of claim 10 made in paragraph 12(a) of the Office Action mailed 02/26/03 (paper no. 13) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

10) The rejection of claims 1-3, 10-13 and 15 made in paragraph 17 of the Office Action mailed 02/26/03 (paper no. 13) under 35 U.S.C. § 102(a) as being anticipated by Ngampasutadol *et al.* (*In*: *Abstracts of the Eleventh International Pathogenic Neisseria Conference*, (Ed) Nassif X *et al.* Nice, France, 1998, p. 159) as evidenced by Rice *et al.* (US 5,476,784) ('784), is withdrawn in light of Applicants' submission of a Declaration under 37 CFR § 1.131 showing that the invention was conceived and completed prior to the publication of the applied abstract.

11) The rejection of claims 1-15 made in paragraph 19 of the Office Action mailed 02/26/03 (paper no. 13) under 35 U.S.C. § 103(a) as being unpatentable over Ngampasutadol *et al.* (*In*: *Abstracts of the Eleventh International Pathogenic Neisseria Conference*, (Ed) Nassif X *et al.* Nice, France, 1998, p. 159) and Tam (In: Peptide Antigens: A Practical Approach. (Ed) Wisdom G.B. IRL Press, Oxford University Press, New York, 1993, pp. 83-90), is withdrawn in light of Applicants' submission of a Declaration under 37 CFR § 1.131 showing that the invention was conceived and completed prior to the publication of the applied abstract.

Rejection(s) Maintained

12) The rejection of claims 1, 3 and 9-15 made in paragraph 10 of the Office Action mailed 02/26/03 (paper no. 13) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 6 of the US patent 5,476,784 ('784); claims 1-9 and 11 of US patent 5,939,067 (Rice *et al.*) ('067), and claims 1-4 of the US patent 6,099,839 (Rice *et al.*) ('839), is maintained for reasons set forth therein and below under paragraph 20.

13) The rejection of claim 13 made in paragraph 12(b) of the Office Action mailed 02/26/03 (paper no. 13) under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Applicants point to page 26, lines 19-25 of the specification and state that 'the characteristics of HB 11311' in the claim refers to 'the immunological reactivity exhibited by the anti-idiotypic antibodies produced from the monoclonal antibody that has been assigned the ATCC accession number HB 11311'.

Applicants' argument has been considered, but is non-persuasive. By the use of the limitation 'the characteristics of HB 11311' in the claim, Applicants are not distinctly claiming the subject matter, because the limitation includes characteristics more than or other than the immunological reactivity. It is suggested that Applicants replace the recitation with --the specific immunological reactivity of HB 11311--.

14) The rejection of claims 9 and 14 made in paragraph 12(c) of the Office Action mailed 02/26/03 (paper no. 13) under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Applicants point to page 20, lines 14-17 of the specification and contend that 'multiple antigen peptide' is adequately described, which description would be meaningful to one of skill in the art as of the filing date of the application.

Applicants' argument has been considered, but is non-persuasive. What is described at lines 14-17 of page 20 is the 'MAP' or the 'multiple-antigen peptide'. In order to distinctly claim the subject matter of the claim, Applicants should replace the limitation 'multiple antigen peptide' with --multiple-antigen peptide (MAP)-- in the claim.

15) The rejection of claim 2 made in paragraph 12(d) of the Office Action mailed 02/26/03 (paper no. 13) under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

With regard to the indefinite and confusing recitation 'DE_GLF', Applicants point to page 9, lines 3-5 and Figure 5 of the specification and assert that the specification clearly shows that '_' in the recited peptide sequence represents a position in the sequence in which 'any amino acid residue can be included'.

Applicants' argument has been considered, but is non-persuasive. A review of the specification at page 9, lines 3-5 and Figure 5 indicates that the notation '_' within the recited peptide sequence was not equated to 'any amino acid residue'. In the absence of a precise description, it is not clear whether the notation represents a gap within the sequence. The rejection stands.

16) The rejection of claim 6 made in paragraph 12(e) of the Office Action mailed 02/26/03 (paper no. 13) under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for

reasons set forth therein and herebelow.

Applicants point to page 19, lines 23-27 of the specification and contend that the recitation 'tail' refers to cyclic peptide mimics. However, this part of the specification does not equate 'tails' to 'cyclic peptide mimics', rather states that cyclic peptide mimics may comprise one or more tails. What is encompassed in 'tails' is still not clear.

17) The rejection of dependent claims 4-10 and 15 made in paragraph 12(f) of the Office Action mailed 02/26/03 (paper no. 13) under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein.

18) The rejection of claims 1, 3 and 9-15 made in paragraph 14 of the Office Action mailed 02/26/03 (paper no. 13) under 35 U.S.C. § 102(e) as being anticipated by Rice *et al.* (US 6,099,839) ('839), is maintained for reasons set forth therein and herebelow under paragraph 20.

19) The rejection of claims 1, 3 and 9-15 made in paragraph 15 of the Office Action mailed 02/26/03 (paper no. 13) under 35 U.S.C. § 102(e) or 102(a) as being anticipated by Rice *et al.* (US 5,939,067) ('067), is maintained for reasons set forth therein and herebelow under paragraph 20.

20) The rejection of claims 1, 3 and 9-15 made in paragraph 16 of the Office Action mailed 02/26/03 (paper no. 13) under 35 U.S.C. § 102(b) as being anticipated by Rice *et al.* (US 5,476,784) ('784), is maintained for reasons set forth therein and herebelow.

Applicants acknowledge that the three cited patents disclose anti-idiotypic antibodies and fragments thereof useful in methods and compositions for the prevention and treatment of *N. gonorrhoeae* infections. Applicants state that the instant invention teaches novel immunogenic peptides that mimic conserved gonococcal epitopes and their use in the prevention and treatment of gonococcal infection. Applicants assert that the peptide mimics are not binding fragments of anti-idiotypic antibodies, and that the latter do not render obvious the peptide mimics of the instant invention. Applicants point to column 5, lines 30-37 of the '784 patent and acknowledge that the patents do teach 'fragments', such as, Fab' fragments, F(ab')2 fragments; F(v) fragments, which comprise one or more CDR, heavy chain monomers or dimers, light chain monomers or dimers, dimers consisting of one heavy and one light chain and the like. Applicants submit that one of ordinary skill in the art would know that these fragments typically contain more than 50 amino acid residues. Applicants state that the peptide mimics of their invention are a linear or cyclic chain of

amino acids, usually at least 4 and less than 50 amino acids in length, which exhibit an immunological antibody binding profile similar to that of a known epitope. Applicants contend that the '784, '067 and '839 patents do not discuss peptide mimics. With regard to the anticipatory rejection, Applicants assert that the '839, '067 and '784 patents do not specify any peptide sequences that correspond to those disclosed in the instant invention. Applicants further submit the Rice Declaration which provides the CA1 VH or CA1 LH sequence data in comparison with the amino acid sequence of one of the peptides disclosed in the instant invention, PEP1. With this, Applicants conclude that the peptides of the instant invention have no structural similarity with any anti-idiotypic fragment or subunit disclosed in the '784, '067 and '839 patents. Applicants argue that: a) the peptide mimics claimed in the instant invention were generated by selecting for immunogenic peptides from a library of random peptides, which are not derived from the anti-idiotypic antibodies of the three cited patents; and b) the chemical composition and purity of the synthesized peptides can be precisely defined and reproduced, since they involve only a small number of amino acid residues as compared to anti-idiotypic antibody fragments, which are typically much longer amino acid sequences. The Declaration also describes multiple preferred uses of the peptide mimics.

Applicants' arguments have been carefully considered, but are non-persuasive. Contrary to Applicants' arguments, the instant claims are not limited to PEP1, or to a peptide mimic of any definite structure. As claimed currently, the peptide mimic of the instant claims is not structurally defined. What is claimed in the instant claims is a generic peptide mimic of a conserved gonococcal epitope as recited, which is neither identified by its structural composition nor by its size or molecular weight. Instant claims contain a functional limitation without reciting any structure. The amino acid sequence of PEP1 is not a part of the instant claims, as presented currently. Since the peptide mimic is not identified by one or more structural limitations, the only limitation that needs to be met by a prior art molecule is that it must qualify as a 'peptide mimic' as recognized by those of skill in the art, and it must have the recited function, i.e., the immunological specificity to oligosaccharide epitopes of *N. gonorrhoeae* which are not present in human blood group antigens. The prior art anti-idiotypic antibody fragments meet the product as claimed. The instant specification at page 12, lines 4-6 describes 'peptide mimic' as meaning 'a peptide which exhibits an immunological antibody binding profile similar to that of a known epitope'. This description in the

specification does not exclude antibody fragments from the scope of 'peptide mimics'. In the absence of a specific closed definition in the instant specification, a limitation is to be given a reasonably broad interpretation. See MPEP 2111. The court has held that the PTO is not required, in the course of prosecution, to interpret claims in applications in the same manner as a court would interpret claims in an infringement suit. Rather, "the PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification". The Office's interpretation of a 'peptide mimic' or a peptide mimetic is based on the art-recognized description of the limitation. A review of relevant art indicates that antibodies and antibody fragments having the binding portion are recognized in the art as peptide mimics or mimetics. For instance, Griffiths (US 2003/0026764 A1) disclose that the term 'antibody fragment' encompasses peptide mimics or peptides that mimic the hypervariable region; any synthetic or genetically engineered proteins that act like an antibody by binding to a specific antigen; Fv fragments consisting of the variable regions of the heavy and light chains; single chain polypeptide molecules in which light and heavy chain variable regions, i.e., sFv proteins; and minimal recognition units consisting of the amino acid residues. See section [0021]. Granoff *et al.* (US 6,048,527) described peptide mimetics to include peptides, proteins and derivatives thereof, synthetic peptides, antibodies, including *anti-idiotype* antibodies (see column 6, lines 23-33 of Granoff *et al.*), wherein the term 'antibody' encompasses F(ab')2 fragments, F(ab) molecules, Fv fragments, single domain antibodies and functional fragments thereof, which 'exhibit immunological binding properties of the parent antibody molecule' (see second full paragraph in column 6 of Granoff *et al.*). As Applicants readily acknowledge, the cited patents did teach such functional anti-idiotypic antibody 'fragments', i.e., Fab' fragments; F(ab')2 fragments; and F(v) fragments, and the like. Thus, the prior art antibody fragments, having the disclosed immunological specificity, inherently qualify as 'peptide mimics'. The three prior art patents do not exclude from the scope of their disclosure anti-idiotypic antibody fragments that are 4 to 49 amino acid-long. It should be noted that the structural feature, i.e., the amino acid sequence of PEP1, upon which Applicants now rely is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are

not read into the claims. See *In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993)*. Furthermore, by the statement that 'peptide mimics claimed in the instant invention were generated by selecting for immunogenic peptides from a library of random peptides', Applicants are submitting a product-by-process line of argument. It should be noted that instant claims are not limited to the manipulations of the alleged step(s), but only the structure. MPEP § 2113 states:

> [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)* (citations omitted).

A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. Applicants have not shown that the alleged difference(s) in the process results in a product that is structurally different from the product of the prior art. In the instant case, Applicants have not shown that the underlying structure of the prior art product differs from that of the instantly claimed product. The rejection stands.

Relevant Art

21) The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

- Ruoslahti *et al.* (US 5,051,408) describe peptide mimics or peptidomimetics to be molecules that mimic the activity of a peptide, or a protein such as an antibody or a fragment thereof, such as an Fv, single chain Fv, Fd or Fab fragment of an antibody, which contains a binding portion. The term 'peptide' is described as broadly encompassing peptides, proteins, fragments of proteins and the like, having a cyclic or linear conformation. See second full paragraph in column 9.

- Metchetner *et al.* (US 6,479,639) disclosed that anti-idiotypic antibodies and their fragments mimic the antigen specificity of the original antibody and therefore serve as vaccines (see third full paragraph in column 9).

- Ferrone (US 5,780,029) disclosed that antiidiotypic antibodies of the internal image type which mimic the initial antigen can substitute for the antigen therapeutically. See last paragraph in column 1.

Remarks

22) Claims 1-15 stand rejected. Claim 16 is free of prior art currently of record and is allowable.

23) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center receives papers 24 hours a day, seven days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

25) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.45 a.m to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November, 2003

S. DEVI, PH.D.
PRIMARY EXAMINER